K063616

Summary of Safety and Effectiveness
Trident® II Acetabular System

DEC 2 0 2006

Proprietary Name:	Trident® II Acetabular System
Common Name:	Artificial Hip Replacement Components - Acetabular
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation Number:	21 CFR §888.3353
Device Product Code:	LZO, MEH
For Information Contact:	Manal Morcos, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5020 Fax: (201) 831-6038
Date Summary Prepared:	October 10, 2006

Description:

This Special 510(k) submission is intended to add the Trident® II Acetabular System. This system is a minor modification to the locking mechanism of the predicate Trident® Acetabular System.

Intended Use:

The Trident® II Acetabular Shells described in this 510(k) submission are single-use sterile devices intended for cementless fixation within the prepared acetabulum. They are compatible with Trident® II X3® Polyethylene bearing inserts, which are also the subject of this submission. If additional fixation is desired, the dome screw holes, if present, have been designed to accept Howmedica Osteonics 6.5mm or 5.5mm bone screws.

The Trident® II Acetabular Shells described in this 510(k) submission are single-use sterile devices intended for cementless fixation with the mating Trident® II X3® Polyethylene Inserts.

Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Substantial Equivalence:

The subject Trident® II Acetabular System shares the same intended use, materials, and basic design concepts as that of the currently available acetabular components of the Trident® Acetabular System. Mechanical testing demonstrated comparable mechanical properties to the predicate components and substantial equivalence to these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Mr. Manal Morcos
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

DEC 2 0 2006

Re: K063616
Trade/Device Name: Trident® II Acetabular System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: December 4, 2006
Received: December 5, 2006

Dear Mr. Morcos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Trident® II Acetabular System

The subject Trident® II Acetabular Shells are intended for cementless fixation within the prepared acetabulum. The subject Acetabular shells intended for use with mating Trident® II X3® Polyethylene Inserts.

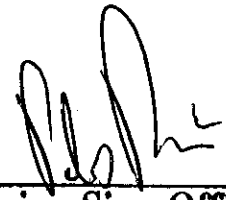
Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063616